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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,703	06/27/2000	IAN ROSS DOYLE	017227/0157	9876

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/486,703	DOYLE ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-9,12,39 and 41-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 7, 8, 9, 12, 39 and 41-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 3-25-05 has been entered into the record. Claims 1, 4, 7, 8, 9, 12, 39 41, 42-50 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

Claims 3 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of the cancellation and amendment of the claims.

Claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 37, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection is withdrawn in view of the amendments to the claims.

Claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 37, 38, 39, 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in part as set forth directly below.

As to claims 1, 3, 4, 6, 7, 8, 9, 11, 12, 37, 38 and 39, the claims recite "which mammal is not exhibiting a symptom specific to lung damage". The specification does not teach which symptoms are specific to lung damage and therefore the metes and bounds of the patient population provided by this negative exclusion cannot be ascertained is withdrawn based on the amendments to the claims.

As to all the claims, the term "the body fluid" lacks antecedent basis in the independent claims is withdrawn in view of the Amendment to the claims.

Rejections Maintained

Claims 8, 9, 12, 39 and 41-43 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 8, and dependent claims 9, 12, and 43, the claims as currently drafted still makes no sense. The method states monitoring for changes in the extent of lung damage which requires a priori knowledge of the presence of lung damage in a mammal, however it is unclear how this is possible in a mammal not exhibiting any visible symptoms of lung damage. If the mammal has lung damage and one is monitoring for changes in the extent of.. would they not necessarily have an outwardly visible symptoms of lung damage. As such, this preamble limitation in context of a mammal already known to have lung damage makes still make no sense.

As to claims 41 and 42, the claims recite methods of diagnosing or monitoring changes in the extent of lung damage "during a period in which the onset of lung damage cannot otherwise by confirmed without the aid of one of more invasive procedures". The specification as filed fails to define or describe the metes and bounds of this time period. This is not persuasive, there is no documentation defining this time period ? Applicants argue that this time period is known to one of skill in the art, but provides no evidence thereof. The tests and procedures are not set forth in the claims and the time period is not set forth in the specificaiton as filed and therefore, the metes and bounds of this time period remain vague and indefinite.

Claims 1, 4, 7, 8, 9, 12, 39 and 41-50 stand rejected under 35 U.S.C. 102(b) as being anticipated by Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen,

Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10-18-00) is maintained for reasons made of record in the Office Action Mailed 9-27-04.

Applicants' arguments have been carefully considered but are not persuasive. Applicant's method is a single step "screening for an increase in the levels of SP-B in a body fluid of the mammal relative to a normal reference level". Applicants submit that Doyle et al do not show any significant difference in SP-B levels between the control group and the other disease group and as such do not meet the limitation of the claim "screening for an increase" in the indicated patient population. This is not persuasive the method step of "screening for an increase" is seen to encompass testing of those individuals that do not have an increase. "Screening" for something is the detection of the presence or absence and as such the measurement in normal individuals and individuals with other disease and on ventilators is screening for an increase in the recited patient populations. There is no positive correlative recitation in the claims that indicates that when an increase is detected then the patient has lung damage. The reflection of the preamble merely indicates the patient population tested. Therefore, Doyle et al does in fact meet the limitation of "screening for an increase". With respect to the new claims (44-50) Applicants previously argued that the art does not teach "early stage lung damage", this was not persuasive, because early stage is defined in the specificaiton to include mild chronic lung damage and therefore the art also appears to meet this limitation. Further, Doyle et al specifically appreciated that "We concluded that SP-B enters the circulation more readily than SP-A in a manner reflecting the severity of lung injury ..." (page 152, see first line of Conclusions). As such, the art specifically teaches that the levels of surfactant proteins specifically correlate with the degree of injury (i.e. lung damage) in a mammal. In contrast to Applicants' arguments, Doyle et al does meet the limitations of the claims as set forth *supra*. Additionally, it is noted that the patient populations of the art are the same patient populations tested and disclosed in the specificaiton (see Example 6, pages 24-26).

New Rejections Based on Amendment

Claims 1, 4, 7, 8, 9, 12, 39 and 41-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1 and dependent claims 4, 7, 8, 9, 12, 39 and 43, the claims now recite "in which mammal there is an absence of outwardly of any visible symptoms of lung damage". The metes and bounds of these outwardly visible symptoms of lung damage cannot be ascertained because it is not defined in the specificaiton as filed. Neither the specification nor the art of record teaches "outwardly visible symptoms of lung damage" and as such, one cannot ascertain the population of individuals to exclude from this mammalian population. As to claims 44-50, the claims recite "early stage lung damage". The term "early" is relative in a time period that is not defined in the specification or the claims. Therefore, therefore the metes and bounds of the time period cannot be readily assessed by either the specificaiton nor the art of record and one skilled in the art would not know if they were infringing upon the claimed method. It is noted that "early stage lung damage" , "in the absence of outwardly visible symptoms of lung damage" and "during a time period in which the onset of lung damage cannot be otherwise confirmed without the aid of one or more invasive procedures" are circularly referenced in the specification (see page 9, lines 21) each referencing the other, for alleged clarification. However, the time periods set forth are not defined in this specification or the art of record and are therefore indefinite and the differences in scope of each compared to the other is not clearly set forth. The outwardly visible symptoms of lung damage are not enumerated and therefore the skilled artisan cannot specifically exclude a population, which is not defined. Outwardly visible symptoms of lung damage and early stage lung damage are time periods that are not defined in the art of record and therefore the excluded or included

population is not immediately apparent to the skilled artisan and one of skill in the art would not know if they were infringing the claim or not.

Claims 8, 9, 12, 39 and 44-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honda (Japanese Journal of Thoracic Diseases, 34 Suppl. Abstract only, December 1996; reference A11 on PTOL-1449 of 6-6-00 in view of Doyle et al (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10-18-00) and Abe et al (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract only, November 1995; reference A10 on PTOL-1449 of 6-6-00).

The claims are drawn to monitoring the changes in the extent of lung damage in mammal in which there is an absence an absence of outwardly of any visible symptoms of lung damage or a method of diagnosing "early stage lung damage". Early stage lung damage as set forth in the specification specifically includes low levels of lung damage and mild but chronic lung damage (see page 9, lines 11-21).

Honda teach the measurement of surfactant proteins A and D in the sera of patients with idiopathic interstitial pneumonia (IIP) by enzyme-linked immunosorbent assay using monoclonal antibodies against humans SP-D and SP-A. Honda teaches that SP-D and SP-A increase in the sera from diseased patients. Honda teaches that the results suggest that SP-D and SP-A, can enter the blood stream easily due to injury at the alveolar-capillary membrane. Further, the serum SP-D and SP-A concentrations appeared to reflect disease activity (see abstract). The patient population having IPP have chronic lung damage and therefore meet the criteria of early stage lung damage. Honda differs by not measuring SP-B levels in serum.

Abe et al teach that the serum levels of SP-A in patients with IIP and that the SP-A levels correlated closely with the clinical course and rose significantly during exacerbations of IPP (see abstract).

Doyle et al teach measuring SpA and SpB to screening for increases in a variety of patients including ventilated patients with no evidence of cardiorespiratory disease and screening of normal individuals (see page 152, Table 1) in sera (i.e. the instant blood). Doyle et al teach that SP-B enters the circulation more readily than SP-A in a manner reflecting the severity of the lung injury (i.e. the instantly claimed lung damage). Doyle et al teach that when taken individually, daily changes in lung function were acutely reflected in concomitant variations in plasma SP-A, SP-B and SP-B/A. (see page 152, first full line of text).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to screen IIP patients for lung damage at the alveolar-capillary membrane by adding the SP-B of Doyle et al to the SP-A and SP-D markers of Honda et al because Doyle teach that SP-B enters the circulation more readily than SP-A and Abe et al and Doyle et al teach that SP-A reflects the severity of the lung injury and correlates closely with disease exacerbations and it is immediately apparent that the levels can be measured/monitored to determine disease activity. As such, one skilled in the art would be able to monitor disease activity in IIP patients using the combination of SP-A, SP-B and SP-D and looking for increased levels of the markers alone or in combination and one skilled in the art would readily expect that SP-B in the serum would increase because Doyle teach that SP-B enters the circulation more readily than SP-A and Honda teaches that both SP-A and SP-D levels are increased and Abe et al teach that SP-A levels closely correlate with disease activity.

Status of Claims

All claims stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645